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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndl	0050/49860	8414

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/937,313	BERNDL ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *10/5/07*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. It is unclear what is being claimed in the process of claims 25-28. The preamble indicates that the method forms a free-flowing powder, comprising pharmaceutically acceptable polymer, a liquid and 10-50% by weight of a surfactant active compound, where the liquid is added to the free-flowing powder. How can a powder remain free flowing once a liquid has been added to it? Is the claim drawn to a pharmaceutical dosage from comprising the free flowing polymer or an entirely different pharmaceutical presentation that as of yet, has not been presented? Does the liquid evaporate during the spray-drying process? Is the liquid a residual? These claims are confusing and require action.

5. For the purposes of prosecution the claim will be interpreted as a method comprising a liquid that somehow remains a free flowing.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 10-12,14,17,19,20 and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Guzi et al (USPN 4,127,422 hereafter '422). The claims are drawn to a process for making a free-flowing excipient comprising spray drying a solution comprising a pharmaceutically acceptable polymer and 10-50% by weight of a surface-active agent.

8. The '422 patent teaches a method of making an excipient comprising spray-drying a solution comprising 15-40 % by weight of a nonionic dispersing agent, and a polymer such as N-vinylpyrrolidone (col. 2, lin. 20-60). The nonionic dispersing agents have an HLB greater that 11, specifically from 12-18 (col. 3, lin. 5-10). The N-vinylpyrrolidone has a K-value from 15-21 (example 9). The excipient comprises a pigment (examples). The formulation is also processed with a concentration of water that is removed during processing to result in a dry powder material (claims). After spray drying the powders are ground through a 1/16-inch (12-mesh screen (examples).

9. Regarding the drop point of claim 11, although the reference is silent to a specific drop point, the reference teaches surface-active compounds that are similarly identified in Applicant's specification. As such all of the inherent properties such as drop point are encompassed by the surfactants of the '422 patent. The instant specification identifies polyoxyethylene ethers and

fatty acids as useful in the invention. These are all disclosed by the prior art. It is the position of the Examiner that these polymers would inherently meet the limitations of the claims.

10. These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 10-12,14-20,22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Guzi, Jr. et al (USPN 4,127,422 hereafter '422) in view of both Staniforth et al (USPN 5,858,412 hereafter '412) and Zeligs et al (USPN 6,086,915 hereafter '915). The claims are drawn to a process for making an excipient comprising spray drying a composition comprising 10-50% of a surfactant and a vinylpyrrolidone polymer.

14. As discussed above the '422 patent discloses a method of making an excipient comprising spray drying a combination of surfactants and polymers of vinylpyrrolidone. The

surfactants can be selected from the group consisting of ethoxylated fatty acid esters and polyoxyethylene fatty glycerides (col. 3, lin. 30-40). The reference does not disclose the specific surfactant so of claims 15 or 16 yet suggest similar polymers in similar concentrations. The inclusion of these surfactants into microparticulate formulations is well known in the art as can be seen in the '412 and '915 patents.

15. The '415 patent discloses microparticulate formulation comprising various surfactants including polysorbate 40, an ethoxylated sorbitan fatty acid ester (col. 11, lin. 25-30), in a concentration up to 20% (col. 13, lin. 47-52, claim 24). The particles are spray dried (col 14, lin. 35-39). The resulting particles measure from 10-500 microns (col. 14, lin. 58-64). The formulation further comprises up to 50% adjuvants such as polyvinylpyrrolidone (col. 18, lin. 53-58). It would have been obvious to include the surfactants of the '415 patent in order to improve the compressibility of the resulting microparticles.

16. The '415 patent also suggests the inclusion of castor oil derivatives as possible surfactants (col. 11, lin. 34). The inclusion of specific castor oil derivative are well known in the art as seen in the ''915 patent. The '915 patent disclose a microparticle carrier formulation comprising 10-40% polyvinylpyrrolidone and 5-20%, an ethoxylated castor oil (col. 12, lin. 35; col. 16, lin. 17-27). The skilled artisan would have been motivated to include the surfactants of the '415 patent in order to improve the stability of the spray dried particles as well.

17. One of ordinary skill in the art would have been motivated to combine the surfactants of the '415 and '915 patents in order to provide improved stability and compressibility of the microparticles resulting from the spray drying. It would have been obvious to combine these

components in order to provide an improved method of making a carrier composition with improved stability.

18. Claims 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Guzi et al (USPN 4,127,422 hereafter '422). The claims are drawn to method of making a free-flowing powder comprising spraying a composition comprising a water-soluble polymer and a surface-active agent.

19. As discussed above the '422 patent discloses a method of making a free flowing powder comprising a spraying a composition comprising a nonionic surfactant, and polyvinylpyrrolidone. The reference however discloses particle size outside of the claimed range. After spray-drying the particles are ground through a 1/16inch screen. This would indicate that particles were roughly as large as 1586 microns are present in the final product. However since smaller particles must also be present in order to have fit through the mesh screen. It is the position of the Examiner that some if not most of the particles would be with within the range of the instant claims. It would be obvious to one of ordinary skill in the art to found particles ranging from 10 microns to 1 mm in the resulting free flowing excipient given the spraying and grinding techniques disclosed in the reference and known in the art.

20. With these aspects in mind it would have been obvious to find particle in the final pigment product within the range of the instant claims. It would have been obvious to find some particles within the range of the instant claims since the largest particles allowed through the screen are up to 1500 microns, while smaller particles would pass through the screen uninhibited.

21. Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Kolter et al (UPNS 6,066,334 hereafter '334). The claims are drawn to a method of making an excipient comprising 10-50 % of a surfactant and a polymer of polyvinylpyrrolidone, wherein the formulation does not comprise a pigment.

22. The '334 patent discloses a redispersible microparticle formulation comprising polyvinylpyrrolidone and up to 10% of a surfactant (abstract; col. 3, lin. 32-35). The polyvinylpyrrolidone has K-values from 30-50 (col. 3, lin. 4-12). The resultant particles have an average size of 1000 microns and are spray-dried (example 1). The formulation further includes binders, lubricants and further bulking agents (col. 4, lin. 51-65), yet is free of pigments.

23. Although the reference indicates that the emulsifiers are present in a concentration up to 10%, they are not exemplified to this range. However the wide range of the concentration would be within the level of ordinary skill of an artisan to optimize in order to arrive at the presently claimed invention. The general conditions of the claims have been met, specifically a process for making an excipient comprising spray drying a composition comprising polyvinylpyrrolidone having K-values from 30-50, and at least 10% of a surfactant. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

24. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

25. With these things in mind it would have been obvious to optimize the ranges of the '334 patent in order to provide a more stable microparticle excipient composition that is free of pigment.

Response to Arguments

26. Applicant's arguments, see Appeal Brief, filed 6/25/07, with respect to the rejection(s) of claim(s) 10-12,14-28 under USC 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Guzi under 102 (b) and Staniforth, Zelig and Kolter under 103 (a).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER